

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

ROBIN MARIE WARREN and
LONNY WARREN,

Plaintiffs,

v.

Case No: 8:19-cv-2657-T-60JSS

C. R. BARD, INC.,

Defendant.

**ORDER GRANTING IN PART AND DENYING IN PART “PLAINTIFF
WARRENS’ MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY,
OR IN THE ALTERNATIVE, TO EXCLUDE CERTAIN OPINIONS AND
TESTIMONY OF PATRICK CULLIGAN, MD”**

This matter is before the Court on “Plaintiff Warrens’ Motion to Exclude the Opinions and Testimony, or in the Alternative, to Exclude Certain Opinions and Testimony of Patrick Culligan, MD” and their memorandum in support, filed on May 13, 2019. (Docs. 41; 42). On May 28, 2019, Defendant C.R. Bard, Inc. filed its response in opposition to the motion. (Doc. 48). On June 3, 2019, Plaintiffs filed a reply. (Doc. 50). After reviewing the motion, response, reply, court file, and record, the Court finds as follows:

Background

This case is one of thousands of similar cases filed since approximately October 2010.¹ Plaintiffs Robin Marie Warren and Lonny Warren directly filed this

¹ In the seven MDLs, over 100,000 cases have been filed, approximately 15,000 of which are in the Bard MDL. See MDL 2187 (C.R. Bard) Member List of Cases, <https://www.wvsc.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187>; MDL 2325 (American Medical

product liability case in the Southern District of West Virginia as part of the multidistrict litigation (“MDL”) entitled *In re: C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187. The case was not resolved by the MDL transferee court (“MDL Court”), and it was transferred at the conclusion of the coordinated pretrial proceedings as part of Wave 8.

On February 21, 2011, Ms. Warren was implanted with the Avaulta Solo Anterior Synthetic Support System (“Avaulta”) device at a hospital in Brooksville, Florida. The Avaulta device was designed and manufactured by Defendant. On April 28, 2016, Plaintiffs filed suit directly in the MDL using a short-form complaint, alleging the following claims: Negligence (Count I), Strict Liability – Design Defect (Count II), Strict Liability – Manufacturing Defect (Count III), Strict Liability – Failure to Warn (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), Loss of Consortium (Count VII), and Punitive Damages (Count VIII).

Analysis

In the motion before this Court, Plaintiffs raise a *Daubert*² challenge to the proposed testimony of Dr. Patrick Culligan, M.D. Plaintiffs argue that Dr.

Systems) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325>; MDL 2326 (Boston Scientific) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326>; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327>; MDL 2387 (Coloplast) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387>; MDL 2440 (Cook Medical) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440>; and MDL 2511 (Neomedic) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511>.

² *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

Culligan's opinions and testimony should be excluded because he was not timely disclosed as an expert witness prior to the court-ordered disclosure deadline. Plaintiffs further argue that certain opinions and testimony should be excluded because they are not based on reliable facts or data.

Timeliness of Expert Disclosure

Plaintiffs argue that Dr. Culligan's opinions and testimony should be excluded because he was not timely disclosed as an expert witness prior to the court-ordered disclosure deadline. The facts regarding the late disclosure do not appear to be in dispute. It appears that Defendant attempted to serve its expert disclosures and reports on March 22, 2019, but due to a typographical error in Plaintiffs' counsel's e-mail address, these documents were not delivered. After learning of the error a few weeks later, Defendant resent the disclosures and expert reports, and it offered to allow Plaintiffs additional time to prepare any rebuttal reports and complete expert depositions.

The Federal Rules of Civil Procedure authorize a court to sanction a party for failing to abide by a scheduling order by prohibiting that party from introducing specific evidence. *See* Fed. R. Civ. P. 16(f); 37(b)(2)(A)(ii). When determining whether such a sanction is appropriate for failing to comply with Rule 26, courts will typically use a three-part test to determine whether noncompliance is substantially justified or harmless: (1) "the explanation for the failure to disclose the witness;" (2) "the importance of the testimony;" and (3) "the prejudice to the

opposing party [if the witness had been allowed to testify.].”³ See *Watkins v. Pinnock*, 802 F. App’x 450, 456 (11th Cir. 2020); *Romero v. Drummond Co.*, 552 F.3d 1303, 1321 (11th Cir. 2008); see also Fed. R. Civ. P. 37(c)(1).

Considering each of these factors, the Court finds that Defendant’s failure to comply with Fed. R. Civ. P. 26(a) was both substantially justified and harmless.⁴ Accordingly, Plaintiffs are not entitled to relief on this ground.

Reliability of Certain Opinions and Testimony

Opinion that Ms. Warren Had a Pre-Implant History of Dyspareunia

Plaintiffs argue that Dr. Culligan’s opinion that Ms. Warren had a pre-implant history of chronic pain including reports of dyspareunia should be excluded because it is not reliable. Specifically, Plaintiffs argue that the opinion is misleading because there are no medical records post-dating Ms. Warren’s hysterectomy that indicate she experienced dyspareunia.

Plaintiffs acknowledge that Dr. Culligan is relying on a sentence taken from a medical note by Dr. Kevin Spires,⁵ dated October 26, 2011,⁶ where Dr. Spires writes that “[Ms. Warren] states she has painful intercourse although this has been a problem since her hysterectomy for endometriosis.” Although Plaintiffs argue

³ The Court notes that the Fourth Circuit Court of Appeals utilizes a five-factor test, which includes “(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to name the witness before trial; and (5) the importance of the testimony.” See, e.g., *Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011).

⁴ The Court notes that after this case was transferred to the Middle District of Florida, the Court set a new discovery deadline of August 28, 2020, which has now been extended to October 28, 2020. See (Docs. 76; 79).

⁵ Dr. Spires was the implanting physician.

⁶ The hysterectomy was performed in 2001, and the Avaulta device was implanted eight months prior to this notation.

that Dr. Culligan's opinion is "misleading" and contradicts the opinion of Plaintiffs' expert witness Dr. Ralph Zipper, M.D., the Court finds that such argument is more appropriately considered as to the weight of the opinion rather than the admissibility of the opinion. As such, the motion is denied as to this ground.

Opinions on the Removal of Exposed Mesh Resolving Ms. Warren's Exposure

Plaintiffs contend that Dr. Culligan's opinions on the removal of exposed mesh resolving exposure are not reliable and should be excluded. Specifically, Plaintiffs point out that Dr. Culligan only references that Dr. Raviender Bukkapatnam performed an excision of eroded mesh on November 17, 2015, ignoring Ms. Warren's January 19, 2019, mesh removal performed by Dr. Christopher Walker. Plaintiffs state that a second procedure is planned, so they believe it is premature to opine that Ms. Warren's symptoms have been resolved. Plaintiffs take issue with Dr. Culligan's opinion that if the removal of remaining mesh is indicated, it would be "relatively straightforward" and there is no reason to expect her conditions will worsen.

Plaintiffs argue that in rendering this opinion, Dr. Culligan has failed to acknowledge any studies or reports that conflict with his own opinions, and that he has failed to offer any explanation as to why he opines to the contrary. Plaintiffs additionally argue that Dr. Culligan is improperly relying on his own personal experience, unsupported by reliable medical or scientific data, which makes his opinions unreliable. Plaintiffs did not depose Dr. Culligan and only cite to a deposition taken on June 9, 2017, in a different case, to support their arguments.

The Court has reviewed Dr. Culligan's expert report and finds that the methodology supporting his opinions is sufficiently reliable. "[D]rawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming" an opinion. *Hall v. Bos. Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *34 (S.D.W. Va. Feb. 27, 2015). Dr. Culligan generally cites to the scientific literature he reviewed and relied upon in drawing his opinions. *See* (Doc. 41-1, Culligan Report). To the extent that Plaintiffs challenge Dr. Culligan's opinions for not relying on certain studies, such challenges go to the weight rather than the admissibility of the opinions. *See, e.g., Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-1617, 2016 WL 2939521, at *33 (S.D. W. Va. May 19, 2016) (denying *Daubert* challenge to Dr. Culligan's opinion based on his alleged failure to account for contrary literature when forming his opinion).

As to Dr. Culligan's opinions on possible future events, the Court finds that the opinions are supported by the record, sufficiently grounded, and admissible.

To the extent that Plaintiffs argue that Dr. Culligan's opinions are unreliable because they are based on personal anecdotal experience not submitted for peer review, the Court finds such argument unavailing. The MDL Court described Dr. Culligan as "an accomplished urogynecologist" who has experience "performing mesh revision surgeries once or twice a month for approximately the last ten years." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 579 (11th Cir. 2014). In fact, "Dr. Culligan has served on university faculties, published peer-reviewed articles concerning mesh and sling procedures, and served as a reviewer for scientific

journals. He also relied upon scientific literature in forming his opinions.” *Id.* Even if every instance of Dr. Culligan’s “personal anecdotal experience” was not specifically submitted for peer review, he is permitted to rely on his clinical experience when forming his opinions. *See, e.g., Trevino*, 2016 WL 2939521, at *33 (denying *Daubert* challenge to Dr. Culligan’s opinions based on his reliance on personal experience). As a result, Plaintiffs’ motion is denied as to these grounds.

General Opinions Regarding the Align

Plaintiffs seek to exclude Dr. Culligan’s general opinions regarding the Align. In response, Defendant concedes that general opinions regarding the Align are irrelevant and inadmissible, and it does not oppose exclusion of Dr. Culligan’s opinions on the Align as long as Dr. Zipper’s opinions are likewise excluded.

The Court previously excluded Dr. Zipper’s general opinions on the Align, which is not the product at issue in this case. *See Warren v. C. R. Bard, Inc.*, No. 8:19-cv-2657-T-60JSS, 2020 WL 1899838, at *2 (M.D. Fla. Apr. 17, 2020). As such, the Court will also exclude Dr. Culligan’s general opinions regarding the Bard Align device. Plaintiffs’ motion is granted as to this ground.

Legal Conclusions

In their motion, Plaintiffs argue that Dr. Culligan should be prohibited from providing any legal conclusions, including that the product was not “defective” and “unreasonably dangerous.” In its response, Defendant acknowledges the MDL Court’s prior rulings and asserts that it does not intend to elicit opinions that draw a legal conclusion. Accordingly, Plaintiffs’ motion is granted as to this ground. *See*

In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). Dr. Culligan is not precluded from offering testimony that uses terms that do not have a separate, distinct, and specialized meaning in the law.

Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

“Plaintiff Warrens’ Motion to Exclude the Opinions and Testimony, or in the Alternative, to Exclude Certain Opinions and Testimony of Patrick Culligan, MD” (Doc. 41) is hereby **GRANTED IN PART** and **DENIED IN PART**, as set forth herein.

DONE and ORDERED in Chambers, in Tampa, Florida, this 1st day of July, 2020.



TOM BARBER
UNITED STATES DISTRICT JUDGE